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Changes: § 3
Deletions: §

LIAISON® Meridian *H. pylori* SA Control Set (REF 318201)

1. INTENDED USE

The DiaSorin LIAISON® Meridian *H. pylori* SA Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® Meridian *H. pylori* SA assay. The performance characteristics of the LIAISON® Meridian *H. pylori* SA Control Set have not been established for any other assay or instrument platforms different from the LIAISON®, LIAISON® XL, and LIAISON® XS.

LIAISON® Analyzer The certificate of analysis gives specific information on the lot of controls, which should be manually entered in the analyzer software prior to loading the control vials on board. For details, refer to the analyzer operator's manual.

LIAISON® XL Analyzer The certificate of analysis bar codes give specific information on the lot of controls and should be read by the hand-held bar code scanner of the LIAISON® XL Analyzer prior to loading the control vials on board. For details, refer to the analyzer operator's manual.

LIAISON® XS Analyzer The certificate of analysis bar codes give specific information on the lot of controls and should be read by the hand-held bar code scanner of the LIAISON® XS Analyzer prior to loading the control vials on board. For details, refer to the analyzer operator's manual.

2. MATERIALS PROVIDED

The following materials are provided in the control set.

Negative Control 2 x 6 mL Ready to use	CONTROL -	Phosphate buffer, BSA, surfactant, 0.1% ProClin® 300 and 0.05% gentamicin sulfate.
Positive Control 6 x 2 mL Lyophilized	CONTROL +	*H. pylori* stool antigen in phosphate buffer, BSA, surfactant, 0.1% ProClin® 300 and 0.05% gentamicin sulfate. Reconstitute with 2.0 mL distilled or deionized water.

ProClin is a trademark of the Dow Chemical Company (Dow) or an affiliated company of Dow.

- Bar Code Labels for Positive Control

Materials required but not provided:

- Pipette capable of delivering 1-2 mL for reconstituting controls
- Glass or polypropylene sample tubes
- Transfer pipette capable of delivering 500 µL

Controls are not kit lot specific and may be safely interchanged between different LIAISON® Meridian *H. pylori* SA reagent integral lots.

3. WARNINGS AND PRECAUTIONS

FOR *IN VITRO* DIAGNOSTIC USE – Not for internal or external use in humans or animals.

GENERAL SAFETY:

- All specimens, biological reagents and materials used in the assay must be considered potentially able to transmit infectious agents. Avoid contact with skin, eyes or mucous membranes. Follow good industrial hygiene practices during testing.
- Do not eat, drink, smoke or apply cosmetics in the assay laboratory.
- Do not pipet solutions by mouth.
- Avoid direct contact with all potentially infectious materials by wearing lab coat, protective eye/face wear and disposable gloves.
- Wash hands thoroughly at the end of each assay.
- Avoid splashing or forming aerosols when handling, diluting or transferring specimens or reagents. Any reagent spill should be decontaminated with 10% bleach solution (containing 0.5% sodium hypochlorite) and disposed of as though potentially infectious.
- Waste materials should be disposed of in accordance with the prevailing regulations and guidelines of the agencies holding jurisdiction over the laboratory, and the regulations of each country.
- Do not use kits or components beyond the expiration date given on the label.

CHEMICAL HAZARD AND SAFETY INFORMATION: Reagents in this kit are classified in accordance with US OSHA Hazard Communication Standard; individual US State Right-to-Know laws; Canadian Centre for Occupational Health and Safety Controlled Products Regulations; and applicable European Union directives (see Material Safety Data Sheet for additional information).

GHS/CLP:

	ProClin®
CAS No.:	55965-84-9
Reagents:	CONTROL - CONTROL +
Classification:	Skin sensitization, Category 1 Aquatic Chronic, Category 3
Signal Word:	Warning
Pictogram:	 GHS07 – Exclamation mark
Hazard Statements:	H317 – May cause an allergic skin reaction. H412 – Harmful to aquatic life with long lasting effects.
Precautionary Statements:	P261 – Avoid breathing mist or spray. P272 – Contaminated work clothing should not be allowed out of the workplace. P273 – Avoid release to the environment. P280 – Wear protective gloves and clothing and eye protection.

4. STORAGE AND STABILITY

Store the controls at 2-8°C upon receipt and prior to reconstitution. The controls are stable until the expiration date on the vial labels when stored at 2-8°C. The controls are stable for 8 hours at room temperature (approximately 18-25°C). The reconstituted positive control may be stored capped at 2-8°C for 28 days. Aliquot and freeze the remaining reconstituted positive control at -20°C for 16 weeks. Reconstituted positive control is stable for 3 freeze/thaw cycles. Indications of possible deterioration include the presence of particulate matter in the liquid or significant deviation from previous results.

5. QUALITY CONTROL

Quality control is required to be performed once per day of use, or according to the guidelines or requirements of local regulations or accredited organizations. It is recommended that the user refer to CLSI C24-A3, and 42 CFR 493.1256 (c) for guidance on appropriate quality control practices.

LIAISON® Meridian *H. pylori* SA controls are intended to monitor for substantial reagent failure. If controls lie outside the expected ranges, calibration should be repeated, and controls and samples retested.

Do not report patient results until control results are within expected ranges. Strict adherence to the instructions of the LIAISON® Meridian *H. pylori* SA assay is necessary to obtain reliable results.

6. PREPARATION AND USE

The LIAISON® Meridian *H. pylori* SA Negative Control is provided ready to use. Allow controls to reach room temperature prior to use and mix thoroughly by gentle inversion. Remove caps from the control and place control into appropriate sample rack type with the barcode showing outward and slide rack into the patient sample area. Return control to the refrigerator immediately after each use.

The LIAISON® Meridian *H. pylori* SA Positive Control is provided lyophilized. Reconstitute the vial with 2.0 mL of distilled or deionized water. Allow the vial(s) to stand for 10 minutes at room temperature, mix gently by inversion until completely dissolved. Ensure any lyophilized material adherent to vial stopper is also dissolved. If using a frozen aliquot, mix gently by inversion prior to use. Transfer approximately 350µL to a glass or plastic tube. Affix the appropriate bar code label to the tube and place onto the appropriate rack with barcode label facing outward. Slide rack into the patient sample area.

Control identification is detected by the barcode label or may be manually programmed into the analyzer. Follow the analyzer operator's manual to start the run. Discard any unused portion of the control remaining in the tube after assaying.

7. LIMITATIONS

Control values for assays other than the LIAISON® Meridian *H. pylori* SA assay have not been established. If users wish to use this control material with other assays, it is their responsibility to establish appropriate ranges.

The performance of other controls should be evaluated for compatibility with this assay before they are used. Appropriate reference ranges should be established for all quality control materials used.

If control values obtained after successful calibration lie repeatedly outside the expected ranges, the test should be repeated using an unopened control vial.

8. ASSIGNED VALUES

The range of concentrations of each control is reported on the certificate of analysis and indicates the limits established by DiaSorin for control values that can be obtained in reliable assay runs.

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